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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/762,522 | 02/05/2001 | Maria Altamura | 205 010 | 4796 |

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Abelman Frayne & Schwab
150 East 42nd Street
New York, NY 10017-5612

EXAMINER

COLEMAN, BRENDA LIBBY

| ART UNIT | PAPER NUMBER |
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1624

DATE MAILED: 04/29/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/762,522 | Applicant(s) ALTAMURA et al. |
| | Examiner Brenda Coleman | Art Unit 1624 |



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Feb 12, 2003
 - 2a) This action is FINAL. 2b) This action is non-final.
 - 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.
- Disposition of Claims**
- 4) Claim(s) 21-33 is/are pending in the application.
 - 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
 - 5) Claim(s) _____ is/are allowed.
 - 6) Claim(s) 21-26, 28-30, 32, and 33 is/are rejected.
 - 7) Claim(s) 27 and 31 is/are objected to.
 - 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) Interview Summary (PTO-413) Paper No(s). _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

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DETAILED ACTION

Claims 21-33 are pending in the application.

This action is in response to applicants' amendment dated February 12, 2003. Claims 21-23, 25-27, 30 and 31 have been amended.

Response to Arguments

Applicants' arguments filed February 12, 2003 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 112, first paragraph rejections labeled d), g) and h) maintained in the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

d) The applicants' stated that the "amendments made to the specification at page 2, lines 3-9 and page 5, lines 15-20 serve to overcome the 35 USC §112, 1st paragraph rejections". The amendment to the specification on page 2, lines 3-9 was not entered and thus the definition of R₈ and R₉ still reads where, R₈ and R₉ together with the N atom to which they are linked to form a piperazine possibly substituted **at** one of its nitrogen atoms by C₁₋₃ alkyl, C₁₋₃ acyl or methanesulfonyl. However, there is only one nitrogen atom which may be substituted. The other nitrogen is already valence satisfied. The paragraph which applicants wish to have inserted spans lines 2-12 on page 2 not lines 3-9. Additionally, the amendment

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which was not entered also contains a typographical error in that the definition of g is a subscript.

- g) The applicants' stated that the "amendments made to the specification at page 2, lines 3-9 and page 5, lines 15-20 serve to overcome the 35 USC §112, 1st paragraph rejections". The definition of R₉ on page 5, line 15 has been amended such that the moiety 4-tetraiodothiopyranyl was amended to 4-tetraiodothiopyranyl. However, at no time can the thiopyranyl be substituted four times with an iodo moiety. It is believed that the applicants intended 4-tetrahydrothiopyranyl.

Applicant is required to cancel the new matter in the reply to this Office Action.

- h) The applicants' stated that the "amendments made to the specification at page 2, lines 3-9 and page 5, lines 15-20 serve to overcome the 35 USC §112, 1st paragraph rejections". The definition of R₉ on page 5, line 16 has been amended such that the moiety 1-oxotetraiodothiopyran-4-yl was amended to 1-oxotetraiodothiopyran-4-yl. However, at no time can the thiopyranyl be substituted four times with an iodo moiety. It is believed that the applicants intended 1-oxotetrahydrothiopyran-4-yl.

Applicant is required to cancel the new matter in the reply to this Office Action.

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2. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled e), j), p), s), t), ae), ah), ak), al), at) and au), maintained in the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejection labeled g), o), y), af), ag), an) and as), maintained in the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

- g) The applicants' stated that "the amendments made to claim 21 serve to overcome the 35 USC §112, second paragraph rejection". However, the g has not been amended to a subscript. (Claims 21-23, 32 and 33)
- o) The applicants' stated that "the amendments made to claim 21 serve to overcome the 35 USC §112, second paragraph rejection". However, the definition of R₄ has not been amended. R₄ is -NR₈R₉.....; -N(R₁₁)CO(CH₂)_hR₁₂.....; or -COR₁₃..... is suggested. (Claims 21-23, 32 and 33)
- y) The applicants' stated that "3-pyridyl-methyl and 4-pyridyl-methyl are not substituents of the phenyl moiety". However, the definition of R₂ in claim 23 has been amended to read as follows: R₂ is phenyl-methyl optionally substituted with up to two substituents selected from the group consisting of chlorine, fluorine, CF₃, OH and CN, or **are** selected from the group consisting of 3-pyridyl-methyl and 4-pyridyl-methyl. Since the only thing in this definition which is plural is the substituents it comes to reason that the substituents are selected from the group

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consisting of 3-pyridyl-methyl and 4-pyridyl-methyl. R₂ is phenyl-methyl optionally substituted with up to two substituents selected from the group consisting of chlorine, fluorine, CF₃, OH and CN; (**semicolon separating the substituents from the rest of the definition of R₂**) or is (**instead of are**) selected from the group consisting of 3-pyridyl-methyl and 4-pyridyl-methyl, is suggested.
(Claims 23, 24, 26, 28 and 30)

- af) The applicants' stated that "Ala (alanine) substituted on the lateral chain (methyl) by the group 4-pyridyl, which is indicated in parentheses" and "that the same nomenclature was used in respect of compounds ix, x and xi which was found acceptable by the Examiner". However, the xiii) species lacks antecedent basis to claim 24 where the definition of R₂ has yet to be clarified with respect to the 3-pyridyl-methyl and 4-pyridyl-methyl. Furthermore, compounds ix, x and xi are Phe(4-F), Phe(3,5-F) and Phe(4-CN), respectively, Phe is alanine substituted on the lateral chain (methyl) by the group phenyl which can be substituted by up to two substituents selected from the group consisting of chlorine, **fluorine**, CF₃, OH and **CN**. The issue at hand is the lack of antecedent basis for the definition of R₂ where R₂ is 4-pyridyl-methyl. (Claim 25)
- ag) The applicants' stated that "Ala (alanine) substituted on the lateral chain (methyl) by the group 3-pyridyl, which is indicated in parentheses" and "that the same nomenclature was used in respect of compounds ix, x and xi which was found

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acceptable by the Examiner". However, the xiii) species lacks antecedent basis to claim 24 where the definition of R₂ has yet to be clarified with respect to the 3-pyridyl-methyl and 4-pyridyl-methyl. Furthermore, compounds ix, x and xi are Phe(4-F), Phe(3,5-F) and Phe(4-CN), respectively, Phe is alanine substituted on the lateral chain (methyl) by the group phenyl which can be substituted by up to two substituents selected from the group consisting of chlorine, **fluorine**, CF₃, OH and **CN**. The issue at hand is the lack of antecedent basis for the definition of R₂ where R₂ is 3-pyridyl-methyl. (Claim 25)

- an) The applicants' stated that "it is evident that in typing the claim, and the corresponding portion of the specification, that the substituent was attributed in error to piperidine instead of to piperazine". However, the definition of R₁₂ in claim 28 lack antecedent basis to claim 21 which claim 28 indirectly depends from. The applicant's also stated that the moiety "4-hydroxy-cyclohexan-1-yl-amino is derived from claim 21 when R₁₂ is an amino-cyclo-hexane optionally substituted by a hydroxy group". Amino-cyclohexane in the definition of R₁₂ is such that the point of attachment is through the cyclohexane not the amino. (Claims 28 and 29)
- as) The applicants' stated that "it is evident that in typing the claim, and the corresponding portion of the specification, that the substituent was attributed in error to piperidine instead of to piperazine". However, the species of claim 29 are

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lack antecedent basis to claim 21 which claim 29 indirectly depends from as stated above. (Claim 29)

Claims 21-26, 28-30, 32 and 33 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

3. With regards to the objection to the disclosure labeled paragraph 5, the applicants' stated that "the definitions of the variable, has been overcome by applicants having now provided the correct structural formula in the specification". However, there was no amendment submitted with respect to the structural formula.
4. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 6 of the last office action, which is hereby **withdrawn**.
5. The applicants amendment is sufficient to overcome the objection under 35 U.S.C. 132 labeled paragraph 7 of the last office action, which is hereby **withdrawn**.
6. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 8 of the last office action, which is hereby **withdrawn**.
7. The applicant's amendments and arguments are sufficient to overcome the newly added 35 U.S.C. § 112, second paragraph rejections labeled a)-c) and e)-l), of the last office action, which

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are hereby withdrawn. However, with regards to the 35 U.S.C. § 112, second paragraph rejection labeled d) under paragraph 9), of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

- d) The applicants' stated that it "has been corrected by amending claim 21 appropriately". However, the definition of f and m is such that the definition refers to f and m in the plural and then in the singular, i.e. f and m are the same or different, and is a number selected from the group consisting of 0, 1 and 2.
(Claims 21, 32 and 33)

Claims 21, 32 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

In view of the amendment dated February 12, 2003, the following new grounds of rejection apply:

Specification

8. The disclosure is objected to because of the following informalities:
- a) the amendment to the definition of R₁ and R₂ in the amendment filed September 18, 2003 is such that R₁ and R₂ are -(CH₂)_rAr₁, where the specification as originally filed is such that R₁ and R₂ are -(CH₂)_rAr. R₁ and R₂ are -(CH₂)_rAr not Ar₁.

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- b) the definition of R₉ on page 5, lines 15-20 includes the moiety N-methansulfonyl-4-piperidinyl, it is believed that the applicants intended N-methanesulfonyl-4-piperidinyl

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 21-23, 32 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason(s) apply:

- a) Claims 21-23, 32 and 33 are vague and indefinite in that it is not known what is meant by the definition of R₈ and R₉, where R₈ and R₉ together with the N atom to which they are linked form a piperazine optionally substituted at the other N atom **substituted** by a C₁₋₃ alkyl, C₁₋₃ acyl or methanesulfonyl.

Claim Objections

10. Claims 27 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays from 8:30 AM to 5:00 PM, on Tuesdays from 8:00 AM to 4:30 PM, on Wednesday thru Friday from 9:00 AM to 5:30 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


Brenda Coleman
Primary Examiner AU 1624
April 25, 2003